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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,432	09/18/2006	Kinsey Maundrell	ARS-131	9885

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,432	MAUNDRELL, KINSEY	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-39 and 46-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-39 and 46-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/18/2006, 3/30/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 4/30/2009. The status of the claims is as follows: claims 28-39 and 46-58 are all pending and under current examination and claims 1-27 and 40-45 are cancelled.

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 4/30/2009 is acknowledged.

Information Disclosure Statement

The IDS submitted 9/18/2009 and 9/18/2007 has been considered in its entirety and a signed copy is attached.

Specification

The disclosure is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code. Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01.

The use of the trademarks including examples GIBCO, SIGMA, FLUKA has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 35, 55, 56 and 57 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a composition of matter comprising an antigen that binds to antibodies that are produced by hybridomas, including specific clones. In claim 35, see (h). Note that such a composition comprising an antigen may be any prion-contaminating solution including those found in nature. While the antibodies may involve the hand of man in their production or isolation, the composition comprising the claimed antigen do not require such an isolated antibody. Note that p. 35 of the instant specification merely describe the antigens as either being an agonist or antagonist of prion conversion. Although the antigens are not identified, they appear to be derived from nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-39, 48-50 and 52-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the specific hybridomas for ECACC Accession Nos. 05021601, 05030901 and 05021603 are required to practice the claimed invention. As such the biological material must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the hybridomas for ECACC Accession Nos. 05021601, 05030901 and 05021603.

The process disclosed in the specification does not appear to be repeatable, it is not clear that the invention will work with commonly available material and it is not apparent if the biological materials considered necessary to make and use the invention is both known and readily available to the public. *It is noted that Applicants have deposited biological material but there is no indication in the specification as to public availability and not address is provided.* Therefore, a deposit at a recognized depository may be made for to overcome this rejection.

If the deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicants, or by an attorney of record over his or her signature and registration number, or by someone in a position to corroborate the facts of the deposit, that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit is a non-Budapest Treaty deposit, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, a statement, affidavit or declaration Applicant, by an attorney of record over his or her signature and registration number, or by someone in a position to corroborate the facts of the deposit would satisfy the requirements herein by stating and providing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) provide evidence of the test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

(e) stating that the deposit will be replaced if it should ever become inviable.

Please note: Rejections under 112, first paragraph, lack of an adequate written description may also arise in these cases if the application as filed does not contain a description to support an amendment to the specification or claims. If an amendment is made to the application, other than the claims, that is not described in the application as filed, this would justify an objection under 35 U.S.C. 112, first paragraph and /or 35 U.S.C. 132 (prohibition against the introduction of new matter) and a requirement that the amendment be canceled.

Claims 35, 55 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to an antigen which to specific antibodies.

The following quotation from section 2163 of the MPEP is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed or through disclosure of a functional characteristic of the claimed genus coupled with a known or disclosed non-functional characteristic (structure) that correlates to the function. In the instant application, no structural characteristics with respect to an

antigen (i.e. sequence) are disclosed that would provide any support for claimed genus of antigens. Note that p. 35 of the instant specification merely describe the antigens as either being an agonist or antagonist of prion conversion but provides no structural characteristics of these antigens.

Claims 35, 55 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a composition of matter of claim 35 and “said antigen” or "an antigen". Note that claim 35 spans p. 3-6 and it is not clear which antigen is being referred to. It is not clear if this antigen is the antigen found in part (j) of claim 35. Appropriate correction or additional clarification is required.

Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a hybridoma produced by the method steps of claim 33. The method steps of claim 33 do not lead to the production of hybridomas.

Claim 31 recites the limitation "said type of PrPsc *sensitive* cells" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 39 recites the limitation "antibody fragment" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-39 and 51-58 are rejected under 35 U.S.C. 102(a, e) as being anticipated by US Application No. 10/269, 010 (or PG PUB 20030096285, hereinafter as "Tso").

Tso describes a composition of matter comprising pharmaceutical carriers with isolated antibodies and antigens (see [0025] and [0089]), meeting the limitations of claims 35(d) and (h), 36-39, 51-58(a). Note that these claims are composition claims and only the components of the composition are examined, not the process of making such products or the intended use. Also because this art meets the structural limitations of the product claims, it must also meet the functional limitations given a chemical is inseparable from it properties. For example, it must also meet that limitation of an antibody that is "*capable* of regulating a biochemical activity" or "*capable* of specifically binding said antigen or a specific portion thereof according to claim 56" (see instant claims 39 and 57).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-39 and 46-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Application No. 10/269, 010 (or PG PUB 20030096285, hereinafter as "Tso") in further view of Bosque et al. and Baron et al.

Tso describes a method for generating an antibody against a lipid raft target comprising isolating lipid rafts from tumor cells, immunizing an animal host by said lipid rafts, producting hybridomas from the immunized animal, selecting said monoclonal antibodies and purifying said selected antibodies (see [0007] and instant claims 28 and 30). Tso claims a method of identifying a tumor target comprising identifying an antigen that binds to the antibodies and determining the partial or full amino acid sequence or nucleic acid sequence of the antigen (see claim 15, claim 55 of this prior art application and instant claims 34). [0089] describes compositions comprising a pharmaceutical carrier and antibodies (see instant claim 35(d), (i), claim 39, claim 51 and claim 58(a)). The author discloses the production of hybridomas via lipid raft immunization (abstract and [0007] and instant claims 43 and 47).

Tso does not disclose using lipid rafts from a type of PrPsc cells (scN2a or N2A) or selecting for antibodies which modulate the conversion of PrPc into PrPsc in a type of PrPsc cells (scN2a or N2A).

Bosque et al., describes ScN2a cells as the most useful cell line for studying the cell biology of prion replication. This line has been used to screen for inhibitors of scrapie formation or PrPc/PrPsc conversion (see introduction, col.1-2). The authors note that comparisons between scrapie-susceptible and resistant cell lines my reveal factors that modulate prion propagation (abstract).

Baron et al., describe a method of making lipid rafts enriched with either the PrPsen or the PrPres (p. 1032-1033). Note that the PrPsen rafts were generated from N2a cells (p. 1032, col. 1). The authors screened for agents which assisted with the conversion of the PrPc into PrPsc protein using the rafts (p. 1033-35).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to use lipid rafts comprising prions from either the PrPsc sensitive or resistant cell in the method of lipid raft immunization taught by Tso. One would have been motivated to do so because such rafts have the advantage of being enriched with prion proteins as taught by Baron et al. Further, the ordinary artisan would have been motivated to use ScN2a cells for screening for antibodies that would modulate PrPc/PrPsc conversion given they are most useful cell line for studying prion replication as taught by Bosque et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is

(571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648
/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646